

Appl. No. 10/798,614
Amdt. Dated May 18, 2009
Reply to O.A. of March 18, 2009

Remarks/Arguments

The pending Office action has predicated the final rejection of the claims at issue on the following errors in law:

The pending Office action erroneously construes recited means-plus-function elements in claim 39 by not referring to the structure disclosed in the specification but rather simply treating the recited elements as recitations of intended function.

Under 35 U.S.C. § 112, ¶6, a claim element recited as "means for" performing a specified function without the recital of structure or material in support thereof "shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." *Id.* In the present application, independent claim 39 recites a device for determining a position and a change in the position of an anatomical structure for use with a surgical navigation system, comprising, *inter alia*, a substrate including means for removably attaching the substrate to an outer surface of a body, wherein the body includes an anatomical structure. (Emphasis added.) Independent claim 56 recites, *inter alia*, that the positional device includes a magnetic transmitter attached to the substrate and a magnetic sensor comprising means for attachment to the anatomical structure. (Emphasis added.) In both claims 39 and 56, the recitations of "means for" immediately followed by recitations of the intended functions of either "attaching the substrate to an outer surface of a body" or "attachment to the anatomical structure" are clearly means-plus-function claim elements that must be construed by the examiner in accordance with 35 U.S.C. § 112, ¶ 6. The specification of the present application discloses examples of structures that are described as performing the function of removably attaching the substrate to an outer surface of an anatomical structure. For example, the specification states that, "The substrate 106 may be mounted to the outer surfaced 111 of the body 112 by an adhesive material, a band, or any other suitable attachment means presently used in conventional surgical operations." U.S. Pat. Pub. No. 2005/0203383, at ¶ 0036, last sentence.

The reasons for rejection presented in the pending Office action, however, clearly do not apply the correct legal standard for either construing these means-plus-function recitations or for considering the patentability of such recitations in view of the applied references. For example, in

Appl. No. 10/798,614
Amdt. Dated May 18, 2009
Reply to O.A. of March 18, 2009

response to the arguments of Applicants' Response dated August 26, 2008, with respect to independent claim 56, it is stated in the present Office action that "Bova teaches that the probe is 'held against the patient' (col. 8, lines 6-7), which would fully satisfy the action of 'attaching' and would also inherently require 'a means for attaching' (i.e. an operator's hand)." Pending O.A. at page 3. In other words, in the reasoning of the pending Office action, the operator's hand disclosed in Bova is (erroneously) considered to meet the means-plus-function structural element recited in claim 56. This is clearly not in accordance with the law of how a means-plus-function claim recitation must be construed, examined, and considered when considering the patentability of the attendant claim.

Further, with regard to claim 39, it is stated in the pending Office action that, "Examiner asserts that Acker's magnetic structure would be just as *capable of* attaching to an anatomical structure as it would be a probe. . . . because the means provided that would allow an attachment to the probe would certainly also allow attachment to the an anatomical structure." Pending O.A. at page 3 (emphasis in original). It is further reasoned in the pending Office action that "the recitation [of the means for attachment to the anatomical structure] would be an example of functional language, and can be met with alternative interpretations of Acker's magnetic structure." Pending O.A. at page 3. Finally, as yet another alternative reasoning, it is argued in the Office action that "Acker explicitly teaches that the magnetic sensor is capable of being attached to an anatomical structure based on the fact that the sensor is attached to the probe, and the probe is inserted in the patient. . . . Therefore, the sensor is attachable to an anatomical structure by means of the probe." Pending O.A. at page 4. All of these rationales presented in the Office action, however, again clearly ignore the fact that the recited "means for attaching..." element is a positive recitation of specific structural significance that must be construed and examined in accordance with 35 U.S.C. § 112, ¶6. Therefore, the rejections of independent claims 39 and 57 have no basis in law.

In fact, as previously argued by Applicants, neither Bova nor Acker, either singly or in combination, disclose or suggest either the "means for removably attaching the substrate to an outer surface of a body" recited in independent claim 39 or the "means for attachment to the anatomical structure" recited in independent claim 56. Rather, Bova teaches that an ultrasound sensor can be

Appl. No. 10/798,614
Amdt. Dated May 18, 2009
Reply to O.A. of March 18, 2009

placed against – without attachment to – the body of a patient and held thereagainst by the ultrasound operator's hand. Acker discloses a magnetic sensor attached to a probe, not to a body of a patient. A person of ordinary skill in the art of surgical navigation systems, however, would readily understand that the examples recited in the specification of the present application do not include the hand of the operator, a magnetic attachment mechanism (which would not be magnetically attracted to the body of the patient), or a probe (which is not intended to be attached to a patient at all). The recited claim elements *must* be construed in light of what an ordinary person in the art would understand the words to mean in view of the description in the specification.

Therefore, the rejections of independent claims 39 and 56 also have no basis in fact.

For at least these reasons, the rejections of independent claims 39 and 56 are based on reasoning that is clearly contrary to law and should be withdrawn, and independent claims 39 and 56, and claims 40-42, 45, 46, 57-60, 63, 77-79, 84, 87, and 89-95 dependent variously thereon, are in position for allowance, notice of which is requested.

Respectfully submitted,

McCracken & Frank LLP
311 S. Wacker
Suite 2500
Chicago, Illinois 60606
(312) 263-4700

May 18, 2009

By: TPR: 4

Thomas P. Riley
Reg. No: 50,556